

REMARKS/ARGUMENTS

Prosecution has been reopened by the Examiner and new grounds for rejection have been entered. Rather than file a request of reinstatement of the appeal with a supplemental brief, the Applicant has amended the claims to further clarify the limitation to "spontaneous fluid transport." The Applicant believes that, in view of the Amendments and the arguments presented below, the pending claims are in condition for allowance.

35 U.S.C. § 112 – Indefiniteness

The Examiner rejected all of the pending claims under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that the Applicant regards as the invention. Contrary to the Examiner's rejection, the term "spontaneous fluid transport" of claim 1 is not indefinite. The limitation is clearly defined in the Specification to mean 'fluid transport without any aid from structure external to the microchannels.' This definition agrees "with the original interpretation by the examiner." Office Action, at 3. As amended, this limitation excludes any structures external to the microchannel or in the microchannel (external to the microchannel surface but contained in the channel itself) that may aid in fluid transport.

In stating the rejection the Examiner indicated that the indefiniteness resulted from different definitions represented by the terms "wicking" and "capillary action." Rather than being separate definitions, the terms "wicking" and "capillary action" are only different ways to describe the flow of the "spontaneous fluid transport." These terms are only descriptions to which the Applicant cited to refute the Examiner's previous 35 U.S.C. § 112 rejection based upon lack of written description.

As stated in the Appeal Brief dated February 2, 2005, the Specification discusses the spontaneous fluid transport in several places throughout the Specification. The Specification describes the spontaneous fluid transport as "wicking" (Specification, at p. 4, lines 24), of "wicking or transporting" (Specification, at p. 10, line 27), and as "capillary action" (Specification, at p. 24, line 21). These descriptions describe the "spontaneous fluid transport" action but do not cause the phrase to be indefinite. Rather, as apparently agreed upon by the Applicant and the Examiner, these phrases support the definition to require 'fluid transport without any aid from structure external to the microchannels.' As stated above, these

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descriptions further support the definition of “spontaneous fluid transport,” as clarified in the claims, to not include any aid from any structures additional to the microchannels.

When the Applicants previously stated that both of the Examiner’s previous interpretations of the phrase “spontaneous fluid transport” were incorrect, he was only referring to the particular phraseology the Examiner had chosen in that office action. While the Applicant does not agree with defining spontaneous fluid transport to include ‘external to the detection article,’ the Applicant agrees with the Examiner’s interpretation of ‘external to the sample’ as put forth in the recent Office Action. In this Office Action the Examiner stated that ‘spontaneous fluid transport’ was “fluid transport without the aid of any structure ‘external to the microchannels’ through with the fluid is transported.” Office Action, at 3. As further clarified herein this phrase also excludes any structure placed in the microchannel.

Claim 1 Is Not Anticipated by Alajoki

Claims 1-3, 5-7, 13, 39-41, 43-46, 53, 54, 60-61, 72-75, 81 and 83-85 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,416,642 to Marja Liisa Alajoki et al. (“Alajoki”). Alajoki, however, does not teach, suggest, or disclose all of the properly construed limitations of claim 1.

The Examiner previously treated the detection apparatus of Alajoki as an imaginary black box. Anything added to the inside of the imaginary box for urging fluid transport, such as an absorbent or a roller, resulted in “spontaneous fluid transport” since an observer could not see that absorbent or roller from outside the box.

The plain language of the claims recites that “spontaneous” refers to a property of the microchannels. Claim 1 states that “the microchannels are adapted to draw a fluid . . . and to provide fluid flow . . . by spontaneous fluid transport and without any aid from any structures additional to the microchannels.” The spontaneous fluid transport is caused solely by the surface characteristics of the microchannel and without any aid from other structures, such as a wick, placed in or on the microchannel. Any article, absorbent, wick, pressure device, or other structure that causes or urges liquid transport in addition to the channel formed by the film surface does not provide “spontaneous fluid transport” as claimed.

The Specification supports this interpretation of the plain language of the claims. The Specification as filed only considered “spontaneous fluid transport” as being caused by the microchannel itself. The Specification states that “[t]he acquisition zone preferably includes two

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or more channels that are capable of wicking a fluid sample into the article by spontaneous liquid transport." Specification, at p. 4, lines 23-25. Moreover, "the acquisition zone 210 preferably includes two or more channels 204 that are capable of wicking a fluid sample into the article 200 by spontaneous liquid transport." *Id.* at p. 26, lines 4-6. "Fluid Transport Film ('FTF') refers to a film or sheet or layer having at least one major surface comprising a microreplicated pattern capable of spontaneously wicking or transporting a fluid." Specification, at p. 10, lines 25-27. "The channels 204 are continuous from the acquisition zone 210 through the detection zone 220 providing continuity of sample flow throughout the detection article 200." *Id.* at p. 28, lines 5-7. Furthermore, "channels 204 provide a means to wick or transport a liquid sample into the acquisition zone 210, between the acquisition zone 210 and the detection zone 220, and into the detection zone 220, by spontaneous and uniform fluid transport, or capillary action, throughout the length of the channels 204." Specification, at p. 24, lines 17-21. As may be appreciated, it is the microchannels themselves, and not any additional structure, whether external or internal to the microchannel, which causes the spontaneous fluid transport of the present invention.

In addition, the Specification does not use the term "wicking" to describe structure placed in the channel. Rather, "[t]he channels of fluid control films usable with the invention preferably provide more effective liquid flow than is achieved with webs, foam, or tows formed from fibers." Specification, at p. 11, lines 19-20. The term wicking is only used to describe the movement of the fluid and not an actual wick. Placement of fibers to wick the fluid along the microchannels is not part of the invention as claimed or recited.

In contrast, Alajoki, as discussed by the Examiner, uses an "absorbent material [that] may be placed in a well channel." Office Action, at 4. Placing a wick inside of the microchannel is external to the microchannel surface. Alajoki therefore does not teach, suggest or disclose "fluid flow of the fluid sample from the acquisition zone to the detection zone along the microchannels by spontaneous fluid transport and without any aid from any structures additional to the microchannels" as recited in claim 1.

The remaining claims 2-3, 5-7, 13, 39-41, 43-46, 53, 54, 60-61, 72-75, 81 and 83-85 depend directly or indirectly on independent claim 1 and are therefore allowable for the same reasons.

Claim 1 Is Not Obvious In View Of Tso

Claims 1-3, 5-9, 41, 46, 60-61, and 83-85 were rejected under 35 U.S.C. 103(a) as obvious in view of U.S. Patent No. 6,613,560 to Jacqueline Tso et al. ("Tso"). One or more sections of Tso relied upon by the Examiner, however, are not prior art to the present application because the parent application to Tso does not provide support in its specification for this information. Tso therefore does not teach, suggest, or disclose all of the limitations of rejected claim 1.

Tso is a continuation-in-part application and by definition contains new subject matter. Tso was filed on February 11, 2000 and claims priority to U.S. Application No. 08/656,281, filed on April 27, 1998, later issued as U.S. Patent No. 6,033,628. The present application was filed on July 7, 2000 and claims priority to Provisional Application No. 60/142,585, filed on July 7, 1999. Tso was filed after the priority date of the present application. Any new matter added to the application that resulted in Tso is not prior art to the present application.

In issuing the rejection, the Examiner relied upon Tso to show that a "sample may be introduced into his [sic] device by spontaneous fluid displacement (Col. 18, lines 54-57)." In the cited section of the Tso specification, Tso states that "the sample may be achieved using any convenient means, including electrokinetic injection, hydrodynamic injection, spontaneous fluid displacement and the like." This particular disclosure, however, is not supported by the specification of the '628 Patent. The '628 Patent specification does not use the term spontaneous. In addition, when describing the movement of the fluid in the liquid phase separation apparatus, the '628 Patent specification states that a variety of injection methods can "be used to introduce fluids into the reservoir compartment via the orifice 34, including pressure injection, hydrodynamic injection or electrokinetic injection." Col. 14, lines 2-5; see also Col. 24, lines 34-36. None of these fluid movement techniques are "spontaneous fluid transport" as claimed in claim 1. The information relied upon by the Examiner from Tso to show spontaneous fluid transport therefore only has a priority date of February 11, 2000 and is not prior art to the present application.

The remaining claims 2-3, 5-7, 13, 39-41, 43-46, 53, 54, 60-61, 72-75, 81 and 83-85 depend directly or indirectly on independent claim 1 and are therefore allowable for the same reasons.

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CONCLUSION

All of the claims remaining in this application should now be seen to be in condition for allowance. The prompt issuance of a notice to that effect is respectfully solicited. If there are any remaining questions, the Examiner is requested to contact the undersigned at the number listed below.

No fee is believed to be necessary for the entry of this paper. Should any fee be required for entry of this paper, the Commissioner is authorized to charge the Faegre & Benson Deposit Account No. 06-0029 and in such event, is requested to notify us of the same.

Respectfully Submitted,

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